UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

10

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]	[illegible]	[illegible]

EXAMINER	
[illegible]	
ART UNIT	**PAPER NUMBER**
1652	4

[illegible]
FOLEY HOAG & ELIOT LLP
PATENT GROUP
ONE POST OFFICE SQUARE
BOSTON MA 02109

DATE MAILED: 08/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/517,491	Applicant(s) Berlin
	Examiner Kathleen Kerr	Group Art Unit 1652

X Responsive to communication(s) filed on 1/25/01 .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

X Claims 1-50 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is approved disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Application Status

1. Claims 1-50 are pending in the instant application.

2. The Examiner notes an apparent typographical error in Claim 12, line 7, which should refer to SEQ ID NO:12 (not 2) since SEQ ID NO:2 does not have 365 amino acids. The following restriction is grouped as if this correction has been made.

Restriction

3. Restriction to one of the following inventions (Groups) is required under 35 U.S.C. 121:

SuperGroup A: Groups I-V (Polypeptides)

Group I. Claims 1-11, 22, 25-32, 34-39, drawn to a fragment of a mammalian (human or mouse) potential phosphatidylinositol-3 (PI3) kinase (RAPT1-like) SEQ ID NO:2 or fragments thereof, classified in class 530, subclass 350.

Group II. Claims 1-13, 22, 25-32, 34-39, drawn to a mammalian (human or mouse) PI3 kinase (RAPT1-like) SEQ ID NO:12 or fragments thereof, classified in class 435, subclass 194.

Group III. Claims 1-11 and 22-24, drawn to fragments of a ubiquitin conjugating enzyme (UCE) SEQ ID NO:14, classified in class 435, subclass 183.

Group IV Claims 1-11 and 22-24, drawn to fragments of an unknown polypeptide SEQ ID NO:16, classified in class 530, subclass 350.

Group V. Claims 1-11 and 22-24, drawn to fragments of an unknown polypeptide SEQ ID NO:18, classified in class 530, subclass 350.

SuperGroup B: Groups VI-X (Nucleic Acids)

Group VI. Claims 14-21 and 40-45, drawn to nucleic acids encoding fragments of a mammalian (human or mouse) potential phosphatidylinositol-3 (PI3) kinase (RAPT1-like) SEQ ID NO:2 or fragments thereof, classified in class 536, subclass 23.1.

Group VII. Claims 14-21 and 40-45, drawn to nucleic acids encoding a mammalian (human or mouse) PI3 kinase (RAPT1-like) SEQ ID NO:12 or fragments thereof, classified in class 536, subclass 23.1.

Group VIII. Claims 14-21, drawn to nucleic acids encoding fragments of a ubiquitin conjugating enzyme (UCE) SEQ ID NO:14, classified in class 536, subclass 23.1.

Group IX. Claims 14-21, drawn to nucleic acids encoding fragments of an unknown polypeptide SEQ ID NO:16, classified in class 536, subclass 23.1.

Group X. Claims 14-21, drawn to nucleic acids encoding fragments of an unknown polypeptide SEQ ID NO:18, classified in class 536, subclass 23.1

SuperGroup C: Groups XI-XV (Antibodies)

Group XI. Claim 33, drawn to antibodies to a mammalian (human or mouse) potential phosphatidylinositol-3 (PI3) kinase (RAPT1-like) SEQ ID NO:2 or fragments thereof, classified in class 530, subclass 387.9.

Group XII. Claim 33, drawn to antibodies to a mammalian (human or mouse) PI3 kinase (RAPT1-like) SEQ ID NO:12 or fragments thereof, classified in class 530, subclass 387.9.

Group XIII. Claim 33, drawn to antibodies to fragments of a ubiquitin conjugating enzyme (UCE) SEQ ID NO:14, classified in class 530, subclass 387.9.

Group XIV. Claim 33, drawn to antibodies to fragments of an unknown polypeptide SEQ ID NO:16, classified in class 530, subclass 387.9.

Group XV. Claim 33, drawn to antibodies to fragments of an unknown polypeptide SEQ ID NO:18, classified in class 530, subclass 387.9.

SuperGroup D: Groups XVI and XVII (Methods of Screening using Polypeptides)

Group XVI. Claim 46, drawn to methods of screening for test compounds using a mammalian (human or mouse) potential phosphatidylinositol-3 (PI3) kinase (RAPT1-like) SEQ ID NO:2, classified in class 435, subclass 15.

Group XVII. Claim 46, drawn to methods of screening for test compounds using a mammalian (human or mouse) potential phosphatidylinositol-3 (PI3) kinase (RAPT1-like) SEQ ID NO:12, classified in class 435, subclass 15.

SuperGroup E: Groups XVIII-XXII (Methods of Screening using Nucleic Acids)

Group XVIII. Claims 47-50, drawn to methods of screening using nucleic acids encoding fragments of a mammalian (human or mouse) potential phosphatidylinositol-3 (PI3) kinase (RAPT1-like) SEQ ID NO:2 or fragments thereof, classified in class 435, subclass 6.

Group XIX. Claims 47-50, drawn to methods of screening using nucleic acids encoding a mammalian (human or mouse) PI3 kinase (RAPT1-like) SEQ ID NO:12 or fragments thereof, classified in class 435, subclass 6.

Group XX. Claims 47-50, drawn to methods of screening using nucleic acids encoding fragments of a ubiquitin conjugating enzyme (UCE) SEQ ID NO:14, classified in class 435, subclass 6.

Group XXI. Claims 47-50, drawn to methods of screening using nucleic acids encoding fragments of an unknown polypeptide SEQ ID NO:16, classified in class 435, subclass 6.

Group XXII. Claims 47-50, drawn to methods of screening using nucleic acids encoding fragments of an unknown polypeptide SEQ ID NO:18, classified in class 435, subclass 6.

4. The inventions are distinct, each from the other, because of the following reasons Distinctness within SuperGroups will first be established followed by distinctness between each pair of SuperGroups.

SuperGroup A (Polypeptides). Groups I-V are related as proteins or fragments thereof disclosed as having similar functions of FKBP/rapamycin complex binding ability. While this may or not be the case, the polypeptides of each of these groups have distinct structures with distinct linear sequences. No general amino acid structure (linear sequence) common to all Groups is disclosed. This is a *restriction* between Groups, not an election of species; these proteins cannot be likened to, for example, a chemical compound with a general structure having different R groups since no common amino acid sequence is defined. Without a common structural feature (i.e. common amino acid sequence), these proteins and their fragments are distinct products and, thus, distinct inventions.

SuperGroup B (Nucleic Acids). Groups VI-X are related as nucleic acids which encode proteins or fragments thereof disclosed as having similar functions of FKBP/rapamycin complex binding ability. As noted above for the proteins, the nucleic acids of SuperGroup B also do not have a common structure (i.e., DNA sequence). As above, this is a *restriction* between Groups, not an election of species. Moreover, each nucleic acid Group contains more than one species of nucleic acid sequence since the claims are drawn to nucleic acids which encode proteins; the degeneracy of the genetic code renders a genus of nucleic acids all with a common structural

feature. Thus, Applicants should not request the commonly quoted "up to ten" nucleic acid sequences be examined since each nucleic acid Group defined herein already includes many more than 10 sequences. These nucleic acids encoding proteins and their fragments are distinct products and, thus, distinct inventions.

SuperGroup C (Antibodies). Groups XI-XV are related as antibodies specific for proteins or fragments thereof disclosed as having similar functions of FKBP/rapamycin complex binding ability. Since these antibody Groups are specific for distinct proteins, these Groups are distinct for the same reasons cited above for Group within SuperGroup A.

SuperGroup D (Methods of Screening using Polypeptides). Groups XVI and XVII are related as similar screening methods using identical method steps. However, these methods use distinct reagents, the polypeptides, as defined above for SuperGroup A. Thus, these Groups are distinct for the same reasons cited above for Group within SuperGroup A.

SuperGroup E (Methods of Screening using Nucleic Acids). Groups XVIII-XXII are related as similar screening methods using identical method steps. However, these methods use distinct reagents, the nucleic acids, as defined above for SuperGroup B. Thus, these Groups are distinct for the same reasons cited above for Group within SuperGroup B.

The nucleic acids of SuperGroup B are related to the polypeptides of SuperGroup A by virtue of the fact that the nucleic acids encode the polypeptides. The nucleic acid molecule has utility for the recombinant production of the polypeptides in a host cell. Although the nucleic

acids and the polypeptides are related, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, nucleic acids can be used for processes other than the production of polypeptides, such as nucleic acid hybridization assays. Therefore, members of SuperGroups A and B are patentably distinct, each from the other.

The polypeptides of SuperGroup A and the antibodies of SuperGroup C are related by virtue of being the cognate antigen (polypeptide) necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are functionally distinct chemical entities and because the polypeptides can be used in processes materially distinct from the process to produce antibody, such as in a enzyme activity assays. Furthermore, the polypeptides can be made using other and materially distinct processes from those used to make an antibody; for example, the enzymes can be made using recombinant *in vitro* techniques while antibody production can be *in vivo*. Therefore, members of SuperGroups A and C are patentably distinct, each from the other.

Related Groups of SuperGroups A and D are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides an be used in a materially

different process of using the product, such as in the production of antibodies *in vivo*. Therefore, members of SuperGroups A and D are patentably distinct, each from the other

Related Groups of SuperGroups A and E are related by virtue of the polypeptides of SuperGroup A which are encoded by nucleic acids used in the methods of SuperGroup E. However, the polypeptides themselves are not used in the methods, nor are they required for the practice of said methods in their isolated forms. Therefore, members of SuperGroups A and E are patentably distinct, each from the other.

Related Groups of SuperGroup B, drawn to nucleic acids, and related Groups of SuperGroup C, drawn to antibodies, are related by virtue of the polypeptides that are encoded by the nucleic acids and necessary for the production of the antibody. However, the nucleic acids themselves are not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, members of SuperGroups B and C are patentably distinct, each from the other.

Related Groups of SuperGroups B and D are related by virtue of the nucleic acids of SuperGroup B which encode the polypeptides used in the methods of SuperGroup D. However, the nucleic acids themselves are not used in the methods, nor are they required for the practice of said methods since the polypeptides can be isolated from natural sources and not recombinantly produced. Therefore, members of SuperGroups B and D are patentably distinct, each from the other.

Related Groups of SuperGroups B and E are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids an be used in a materially different process of using the product, such as in recombinant production of the encoded proteins. Therefore, members of SuperGroups B and E are patentably distinct, each from the other.

Related Groups of SuperGroup C are related to Groups of SuperGroups D and E by virtue of the polypeptides which are antigenic to the antibodies of SuperGroup C, which are used in the methods of SuperGroup D and which are encoded by nucleic acids which are used in the methods of SuperGroup E. However, the antibodies themselves are not used in the methods, nor are they required for the practice of said methods. Therefore, members of SuperGroup C are patentably distinct from SuperGroups D and E, each from the other.

Related Groups of SuperGroups D and E are related by virtue of the polypeptides which are used in the methods of SuperGroup D and which are encoded by the nucleic acids which are used in the methods of SuperGroup E. However, these methods use reagents, either polypeptides OR nucleic acids. Moreover, the method steps are distinctly different between the SuperGroups. Thus, members of SuperGroups D and E are patentably distinct, each from the other.

Election

5. Applicants are advised that the reply to this requirement MUST include an election of the invention to be examined, even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

6. The Examiner notes that if either Groups I or II are found directed to an allowable product, then Groups XVI or XVII, which each are directed to the process of using the respective patentable products, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai*, and *In re Brouwer*). Also, if any of Groups VI-X are found directed to an allowable product, then the related Groups XVIII-XXII, which each are directed to the process of using the respective patentable products, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined. Since Groups drawn to process claims would be rejoined

and fully examined for patentability under 37 CFR 1.104, applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Sequence Compliance

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 CFR 1.821 through 1.825, applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicants must provide an initial computer readable form (CRF) copy of the "Sequence Listing", to match the paper copy filed with the instant application, and a statement that the content of the paper copy filed with the application and the CRF copy filed in response to this action are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(h) or 1.825(d).

The Examiner notes that the instant application is a continuation-in-part of 08/250,795. If the sequence listing of the parent application is identical to the paper copy of the sequence listing filed in the instant application, Applicants can respond to sequence compliance by requesting a transfer of the CRF from the parent application to the instant application. Such a request will also require a statement of sameness that the CRF from the parent application is identical to the paper copy filed in the instant application.

Examiner Notes

8. The Examiner notes a distinct lack of written description for SEQ ID NOs: 16 and 18 in the instant specification. The only mention of said sequences, which the Examiner could find, is in the claims. Applicants are requested to point out particular written description of SEQ ID NOs: 16 and 18 if related subject matter is elected.

9. The Examiner suggests Applicants indicate clearly the origin of species of SEQ ID NOs: 2 and 12 and where such definition can be found in the instant specification. The only definition of species, which the Examiner could find, is a reference to mammalian being mouse and human; however, which sequences are mouse and which are human is not clear upon first glance of the instant specification required for restriction purposes. Moreover, if SEQ ID NOs: 2, 12, and 14 are from full-length sequences that are known in the art, the examination of the instant application would be greatly facilitated by Applicants' identification of GenBank Accession Numbers for said full-length sequences.

Conclusion

10. Applicants are advised that the reply to this action (1) MUST include an election of the invention (Group) to be examined and (2) MUST include a computer readable form of the sequence listing to be fully responsive.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Kathleen M. Kerr whose telephone number is (703) 305-1229. The Examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

PONNATHAPURA ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK

February 26, 2001